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Surgeon vs. Knee Maker: Who's Rejecting Whom?

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IT was a long, fruitful medical marriage that is fast becoming an angry public divorce, one that offers a rare look at a clash between a top-shelf consultant and his corporate patron over patient safety.

For years, Dr. Richard A. Berger designed surgical tools and artificial joints for Zimmer Holdings, trained hundreds of doctors to use its products and talked it up wherever he went. In return, Zimmer, an orthopedic implant maker, helped enrich Dr. Berger, portraying him as a master surgeon and paying him more than $8 million over a decade.

Those days are gone. Dr. Berger started complaining to Zimmer a while back that one of its artificial-knee models was failing prematurely, and he went public recently with a study that he says proves it. Zimmer told him that the problem was not the artificial knee, but his technique, and pointed to data overseas indicating that the knee was safe.

Last year, Zimmer did not give Dr. Berger a new contract. The company says it routinely rotates consultants.

"I trained hundreds of doctors for them and made them tens of millions," Dr. Berger said in interview here, in which he also lambasted Zimmer executives as dissembling, out-of-touch bureaucrats. "So was this just a coincidence? Maybe it was. Maybe it wasn't."

Zimmer executives declined to be interviewed. The company said in a statement that it had thoroughly investigated Dr. Berger's complaints in 2006 and that he had disagreed with its findings.

Amid the booming use of artificial joints in the United States, the breakup between Dr. Berger and Zimmer highlights what experts say is a troubling situation for patients and

doctors: when disputes arise about orthopedic implant safety, there are no independent referees or sources of information because no one tracks the performance of the devices.

"There is no way of knowing who is right because we don't have the data," said Dr. Kevin J. Bozic, a professor of orthopedic surgery at the University of California, San Francisco.

While producers of implanted heart devices have a voluntary system in which outside panels investigate problems, American makers of orthopedic devices do not. Many of the artificial joints that surgeons like Dr. Berger use, including the Zimmer knee at issue, are cleared under law by the Food and Drug Administration for sale without testing in patients. In addition, no one in the country tracks the long-term performance of artificial hips and knees, a $6.7 billion annual business that surged as baby boomers reached middle age.

THOSE with the most to lose are the hundreds of thousands of people who receive an orthopedic device each year.

One patient, Lisé Markham, said she underwent surgery recently to replace a flawed hip just two years after getting it. She said the experience awakened her to how little patients can find out about an implant's track record.

"My doctor knew everything about me, every personal detail, but what did I know on the other side?" said Ms. Markham, who lives in San Diego.

Two years ago, another top Zimmer consultant, Dr. Lawrence Dorr of Los Angeles, alerted surgeons that a company hip model was failing after a few years. Zimmer shot back, saying the problem was Dr. Dorr's technique, not the device. Along with briefly halting sales, it also provided the F.D.A. with data from 12 surgical centers showing that the hip was working well. Based on that, the agency decided to close its investigation, said an F.D.A. spokeswoman, Mary Long.

But in interviews, two doctors who provided Zimmer with supportive data in 2008 said the hip started failing soon afterward in their patients, too. One, Dr. Richard Illgen of the University of Wisconsin, said he now realizes that Dr. Dorr's technique was not the issue, but that Dr. Dorr had just started using the Zimmer hip before other surgeons. Zimmer still defends the product, which is known as the Durom hip.

These days, companies like Zimmer have fewer consultants, part of the fallout from settlements in 2007 by several companies, including Zimmer, of Justice Department charges that consultant payments were used to disguise kickbacks to surgeons. However, relationships with Dr. Berger and Dr. Dorr were not called into question.

ABOUT a decade ago, when the relationship between Dr. Berger and Zimmer began, it was filled with promise. The surgeon, a tall, balding man with a boyish manner, was finishing his fellowship at the Rush University Medical Center in Chicago at the time, one of the country's top centers for joint replacement. The center has had long ties to Zimmer, whose headquarters is about two hours away, in Warsaw, Ind., and the young surgeon quickly came to the company's attention.

"Rich has a very clever set of hands, and because of that he is enabled with the ability to innovate surgical techniques," said Roy Crowninshield, who was Zimmer's chief scientific officer.

Dr. Berger's skills matched Zimmer's marketing strategy. To distinguish itself from competitors, the device maker had started promoting minimally invasive surgery, a technique that uses smaller incisions than traditional surgery. Zimmer trained doctors in the procedure, using its device.

Soon, Dr. Berger, who was then pioneering a type of small-incision surgery that allowed patients to leave the hospital on the day of surgery, became a linchpin of Zimmer's efforts. In 2002, he was prominently featured in a press release about Zimmer's plans to build a training facility for minimally invasive surgery.

"We are clearly excited about Dr. Berger's data," J. Raymond Elliott, the company's chairman and chief executive at the time, stated in the release.

Over the next few years, the physician estimates, he helped train hundreds of surgeons on Zimmer's behalf. His star also rose: he and his technique were featured on "World News Tonight" on ABC, and he was soon performing about 1,000 hip and knee replacements annually, nearly all with Zimmer devices.

But Dr. Berger, who is 47, with energy and self-confidence to spare, also became a lightning rod. Other doctors questioned whether his technique of using such a small incision could be broadly adopted, and interest in his approach fell. The concern was that such a tiny opening left doctors with little room for error.

Dr. Berger brushes off complaints, saying that many surgeons do not have the skill or the patience to learn his technique. "There are lots of reasons that people don't want to do something new," he said.

As he tells it, his relationship with Zimmer frayed over a version of a widely used Zimmer knee, known as the NexGen. The model at issue, called the NexGen CR-Flex, is designed to provide a greater range of motion than the standard NexGen.

Most surgeons implant an artificial knee using a cement-like adhesive to bond the thigh bone to the portion of the device that bends. But some specialists, like Dr. Berger, try to avoid adhesives because the cement can break down and cause device failure. So Zimmer also sells an uncemented version of the CR-Flex that relies instead on the bone naturally fusing with the implant.

Dr. Berger says that he gave the device, which is supposed to last about 15 years, to about 125 patients in 2005, the first full year he used it. But by early 2006, some X-rays showed lines where the implant met the thigh bone, an indication that the device was loose and had not fused completely. Patients could walk, but they were reporting pain, apparently a result of the loose joint.

He says he soon brought the problem to the attention of Zimmer officials, including the company's new top scientist, Cheryl R. Blanchard. Zimmer executives pointed to the success of the NexGen, but the company did not have separate test data on the uncemented flexible model because the F.D.A. had not required the company to study it in patients before selling it.

Later, as more patients complained about the device and Dr. Berger had to replace some of them, he spoke to Ms. Blanchard again, he said. This time, he said, she and other Zimmer officials suggested that his technique was the problem because no other surgeon had complained.

"Suddenly, I went from someone who was their master teacher to someone who didn't know what he was doing," he said.

BY 2007, Dr. Berger, although still a Zimmer consultant, had stopped using the device and had learned, he said, that several other surgeons had also experienced problems with it. But unlike Dr. Dorr, the physician who sent out the alert about Zimmer, Dr. Berger said he initially had hoped to avoid a public showdown with the company. So he followed a more traditional route by performing a study with another Rush surgeon, Dr. Craig J. Della Valle, who was also having to replace the Zimmer knee.

Dr. Berger and Dr. Della Valle first presented their study at a medical meeting last fall and again this year at a national meeting of the American Association of Orthopedic Surgeons. They found that the uncemented Zimmer knee failed early in about 9 percent of some 100

patients studied. Also, the knee exhibited signs of looseness in about half of all patients and has since been replaced in some of them, Dr. Berger said.

But Zimmer was unswayed. In a filing with the Securities and Exchange Commission, Zimmer made note of the study but also pointed to the knee's very positive results in a large database of orthopedic patients in Australia. Officials there confirmed the low failure rate. The company also said that the cement-free CR Flex accounted for only a small fraction — about 2 percent — of its overall knee sales.

Zimmer said that collaboration with surgeons like Dr. Berger was critical to the success of its products. "To date, Dr. Berger remains a valued customer of Zimmer," the company stated.

That may also change soon. Dr. Berger said he was talking with another device maker about consulting and is trying out other products.

As for Zimmer, he said, "I have lost confidence."